

Labeler Code Request

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Overview

- Labeler Code – Who, When & How
- Labeler Code Rejections
- Common Errors
- Mergers and Acquisitions

Labeler Code

The first segment of the NDC is the labeler code and consists of 4 or 5 digits. The labeler code is assigned by FDA.





Labeler Code - When

- Labeler Code Request must be requested when a drug listing must be submitted within 5 days of going into commercial distribution.
 - Labeler Code Request must be submitted and completed prior to drug listings.
- If you do not have to list any drugs with FDA, you do not need to apply for a labeler code .
- Labeler codes that are NOT utilized by listing a drug product are automatically INACTIVATED after 24 months.

Labeler Code

- Companies do not need a Labeler Code for each site.
- DUNS and FEI are site-specific and labeler codes are company-specific.



Labeler Code – How to Request



- **Step 1** – Submit a **NDC Labeler Code Request Document** if you are requesting a new labeler code. **Leave the NDC Labeler Code field blank**

The screenshot shows the 'NDC Labeler Code Request' form. A red arrow points from the text 'Leave the NDC Labeler Code field blank' to the 'Labeler Code' field, which contains the digit '0'. A red error banner at the top right states: '1 ERROR HAS OCCURRED. Labeler Code should be 4 or 5 digits long. (Go to error)'. The form is divided into sections: HEADER DETAILS, LABELER DETAILS, LABELER CONTACT DETAILS, and LABELER CONTACT ADDRESS. The 'Labeler Code' field is located in the 'LABELER DETAILS' section.

HEADER DETAILS

Document Type: * NDC/NHRC LABELER CODE REQUEST

Set ID: * 771c9a4c-cb83-3c05-e053-2a91ab0a54ea [Generate New](#)

Root ID: * 7740429e-594a-04fb-e053-2a91ab0afe04 [Generate New](#)

Version Number: * 2

Effective Date: * 10-02-2018

1 ERROR HAS OCCURRED
Labeler Code should be 4 or 5 digits long. ([Go to error](#))

LABELER DETAILS

Labeler Name: * FDA Company

Labeler DUNS: * 123456789

Labeler Code: * 0

LABELER CONTACT DETAILS

Contact Name: * Pui Huber

Contact Email: * pui@email.com

Contact Phone: * 1-999-999-9999 [Format](#)

Phone Extension: *

LABELER CONTACT ADDRESS

Country: * United States

Street Address: * 101 FDA Drive

City: * Silver Spring

State: * Maryland

Postal Code: * 20903

ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

Labeler Code – How to Request



- **Step 1** – U.S. Agent information is highly suggested for foreign firms.

LABELER CONTACT DETAILS

Contact Name: * Pull Huber
Contact Email: * pull@email.com
Contact Phone: * 1-999-999-9999
Phone Extension: *

[Format](#)

LABELER CONTACT ADDRESS

Country: * India
Street Address: * 101 FDA Drive
City: * Silver Spring
State/Province: *
Postal Code: * 20903

Enter U.S. Agent Information

OPTIONAL

— ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

☐ Same as Labeler Contact Address
Country: * --Select Country--
Street Address: *
City: *
State/Province: *
Postal Code: *

U.S. AGENT

Agent Name: *
Agent DUNS: *
Agent Email: *
Agent Phone: *
Phone Extension: *

[Format](#)

Labeler Code – How to Request



Step 2 - FDA will evaluate the request and may contact the request if any clarification is needed

- 1) Name of the firm requesting a new labeler code - *FDA Company*
- 2) Address and DUNS of firm requesting labeler code - *101 FDA Drive*
- 3) Drug business type of labeler (e.g. manufacturer, distributor, contract manufacturer, repacker, relabeler, analytical lab, etc)- *Distributor*
- 4) Type of drug product(s) (Rx or OTC, also Human or Vet)- *OTC-Human*
- 5) US agent information (if firm is located outside of the United States of America)- *N/A*

(edrls@fda.hhs.gov).



- Physical address should not contain PO BOX Information
- Physical address of the firm **MUST** match the address in D&B

Labeler Code – Assigned



Step 3 - FDA will email the contact person on the request with the assigned number.

eDRLS - Electronic Drug Registration & Listing System

Current Date: 22-OCT-2019
Labeler DUNS: 123456789
Labeler Name: FDA Company
Labeler Code: 12345

Please allow 7-10 business days for your Labeler Code Request to be processed.

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. **To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit [Drug Registration and Listing System](https://www.fda.gov/edrls) or reply back to this email (edrls@fda.hhs.gov).

Labeler Code – Assigned



Step 4 - To **complete the process**, submit an updated labeler code form SPL with the newly assigned number filled in.

HEADER DETAILS

Document Type: * NDC/NHR
Set ID: * 771c9a4c
Root ID: * 93dbd9d1

First segment (NDC/NHRIC labeler code) must match a labeler code associated with the Labeler id (labeler's DUNS Number) in a previously submitted NDC/NHRIC Labeler Code or NDC Labeler Code - Animal Drug SPL document, except for parts. (Go to error)

LABELER DETAILS

Labeler Name: * FDA Company
Labeler DUNS: * 123456789
Labeler Code: 12345

LABELER CONTACT DETAILS

Contact Name: * Puii Huber
Contact Email: * puii@email.com
Contact Phone: * 1-999-999-9999 [Format](#)
Phone Extension:

LABELER CONTACT ADDRESS

Country: * United States
Street Address: * 101 FDA Drive
City: * Silver Spring
State: * Maryland
Postal Code: * 20903

Labeler Code – Rejections

- If you are not required to list drugs
- If you already have a LC assigned
- If your labeler code was automatically inactivated
- If your Information does not match D&B data
- If you are a veterinarian drug manufacturer or distributor
 - Submit an NDC Labeler Code Request-Animal Drug (LOINC Code-72871-7)



When should a labeler code information be updated?



- Information must be updated within 30 calendar days after any change:
 - Physical address, email and other information
- Per § 207.33(c)(2)
- FDA uses this information for official communication regarding the listing.



Mergers & Acquisitions



Merger & Acquisitions are different in each case based on business decisions and contractual agreements.



Company A and B are Merging and they are changing their name to Company C. In addition, they have decided to keep company A's Labeler Code.

- **Company A :**
 - Update their Labeler Code Information to include the new name and any other updates.
 - Drug listing must be updated to include the new Labeler name.
- **Company B :**
 - Discontinue all drug listings associated to their old labeler code
 - Relist the listings under Company C's Labeler Code
 - Labeler Code must be inactivated.



Challenge Question 1

If a company has three establishments, how many labeler codes do they need?

- a) One labeler code 
- b) Two labeler codes 
- c) Three labeler codes (one for each site)

Challenge Question 2



Labeler Code Information including the name, physical address, email address and other contact information must be updated within

- a) 60 days
- b) 90 days
- c) 30 days 
- d) Every June and December



Challenge Question 3

Application Holders/Sponsors that perform no manufacturing process are required to obtain a labeler code.

True or False



Questions?

Contact Us:
eDRLS@fda.hhs.gov